

Applicants: Björck *et al.*
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REMARKS

In the office action dated December 31, 2002, the Examiner: (1) rejects claims 14 –19 and 21 under 35 U.S.C. § 101; (2) claims 14 –16, 18 and 19 under 35 U.S.C. § 102(b); and (3) acknowledges that claims 17 and 21 are free of prior art. Based on the amendments above, and in light of the reasons provided below, Applicants respectfully request that all outstanding rejections be withdrawn.

The Examiner rejects claims 14-19 and 21 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicants respectfully point out that the claims are not directed to naturally occurring products. For example, claim 14 is directed to a protein consisting essentially of domains of protein L having the ability to bind to the light chains of immunoglobulin. Such domains do not correspond to protein L as it occurs naturally in its entirety. Protein L in its entirety comprises some 719 amino acids (Kastern *et al.*, 1992), whereas the sequence referred to in claim 1, (SEQ ID NO: 1) is only 305 amino acids. Similarly, claims 15 and 21 are directed to hybrid proteins consisting essentially of such domains derived from protein L and domains that bind to heavy chains of immunoglobulin G; such heavy chain binding domains are not components of protein L. Thus, the protein of claims 15 and 21 is a hybrid derived from at least two different proteins and not a naturally occurring product. Nevertheless, in order to advance prosecution of this application, claims 14, 15 and 21 have been amended as the Examiner suggested to refer to isolated proteins. This amendment is submitted solely to indicate that the claims are not directed to any proteins that may be naturally occurring. Support for this amendment may, for example, be found in the examples, which describe cloning and expression techniques and thus support claims directed to compositions that are not naturally occurring. Accordingly, the subject matter claimed clearly meets the requirements of 35 U.S.C. § 101.

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The Examiner rejects claims 14-16, 18 and 19 under 35 U.S.C. § 102(b) as anticipated by Kastern *et al.*, 1990. In support of this rejection the Examiner referred to a sequence comparison identified as "sequence search result #2."

At the outset it should be pointed out that sequence search result #2 references three papers Kastern *et al.*, Infect, Immun. 58: 1217-1222 (1990); Björck, Sjöbring and Kastern, J. Biol. Chem., 267:12820-12825 (1992); and Murphy *et al.* DNA Seq. 4:259-265 (1994). It has already been established that the second of these papers is not prior art against the present application, and the Examiner does not cite that reference in the pending office action. The fact that it is not prior art was explicitly acknowledged in paragraph 5 of the office action dated January 29, 2002 where the paper is referred to as Kastern *et al.* (1992). Additionally, the third reference is not cited against Applicants.

Applicants respectfully submit that despite the print out from search result #2 that was forwarded by the Examiner, the other reference, Kastern *et al.* (1990), does not teach, disclose or otherwise suggest the sequence of 305 amino acids corresponding to the sequence set forth in SEQ ID NO:1.

The passage cited by the Examiner at page 1219 columns 1-2 discloses the cloning and sequence determination of a part of protein L. There is no disclosure of the characterization of domains of protein L having the ability to bind to the light chains of immunoglobulins as identified in the present application. Still less is there characterization of protein L as a whole. At most, Kastern *et al.* (1990) discloses a sequence of 220 nucleotides and a corresponding derived amino acid sequence (Figure 5). It also discloses some short peptide fragments and probe sequences. The complete sequence of 305 amino acids cited in the search result is only disclosed in the 1992 paper by Björck, Sjöbring and Kastern, which as noted above, is not prior art against the subject application.

Inherent properties

Further, the nucleotide sequence shown in Figure 5 of Kastern *et al.* (1990) does not correspond to an isolated protein having ability to bind to the light chains of immunoglobulins as now claimed. The sequence corresponds to a fragment of the sequence shown in Figure 2 or SEQ ID NO: 1 of the present application beginning at amino acid 109 and ending at amino acid 182. The sequence in the citation begins part way through domain B2 and ends part way through domain B3 as identified in the present application. This is clearly not a disclosure of a protein consisting essentially of the amino acid sequence of SEQ ID NO: 1 as in claim 14(a), which includes domains B1, B2, B3 and B4. Nor is there any clear disclosure of any of the individual domains B1-B4 as defined in claim 14(b). With regard to claim 14(c), this embodiment is directed to a protein consisting essentially of multiple domains selected from B1, B2, B3 and B4. There is no disclosure of such a domain combination in the citation. Accordingly, the proteins defined in claim 14 are not anticipated by Kastern *et al.* (1990).

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Inherent

It follows from the foregoing arguments that a hybrid based on the protein of claim 14 as defined in claim 15 or 16 and reagent kit or composition as defined in claims 18 or 19 containing such a protein are neither anticipated by nor rendered obvious in light of the cited reference. Moreover, it will be noted that there is no disclosure in Kastern *et al.* (1990) of a hybrid protein of any description including domains that bind to light chains in immunoglobulins and domains that bind to heavy chains as defined in claim 15. It is respectfully submitted that it is improper to assert that such domains would be inherent since there is no disclosure of any hybrid protein in the reference. Equally, there is no disclosure of any reagent kit or composition incorporating an additive or carrier in accordance with claims 18 and 19.

Accordingly, the reference does not disclose the domains B1-B4 of protein L, which have the ability to bind to the light chains of immunoglobulins. It does not make available an isolated protein consisting essentially of such domains or a hybrid protein based upon them.

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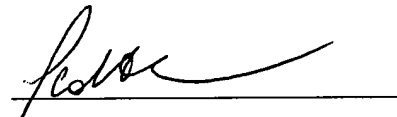
Nor does it give a person skilled in the art any reasonable expectation for identifying the specific domains B1-B4 as providing the ability to bind to the light chains of antibodies.

Accordingly, it is respectfully submitted that the subject matter claimed is not anticipated or rendered obvious by Kastern *et al.* (1990), and the currently pending claims are in condition for allowance.

Applicants submit that no fee other than the enclosed fee for the two-month petition for extension of time is required. However, if any additional fees are necessary or any overpayment has been made, please charge or credit Deposit Account No. 11-0171 accordingly.

If the undersigned can be of any assistance in furthering prosecution of this application, the Examiner is invited to contact him and the telephone number provided below.

Respectfully submitted

A handwritten signature in dark ink, appearing to read 'Scott D. Locke', is written over a horizontal line.

Scott D. Locke, Esq.
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